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ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH AMENDMENTS OF 1986

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Mr. HATCH, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 2595]

The Committee on Labor and Human Resources, to which was referred the bill (S. 2595) "Alcohol, Drug Abuse, and Mental Health Amendments of 1986," having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

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I. SUMMARY OF THE BILL

As reported by the Committee, S. 2595 amends title V of the Public Health Service (PHS) Act to reauthorize the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA) for 5 years. The bill also changes the name of the Alcohol, Drug Abuse, and Mental Health Adminis-

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tration (ADAMHA) to the National Institutes on Alcohol, Drugs, and Mental Health (NIADMH). S. 2595 requires the publication every 3 years rather than every year of a report to Congress on prevention activities undertaken by NIADMH and its three institutes. The bill provides authority for the institutes of NIADMH to deal with public health jurisdictions within their respective jurisdictions, and authorizes other amendments relating to animal research standards, the use of volunteers by the research institutes, and the recodification of the mental health components of the PHS Act under title V.

S. 2595 requires the Secretary of HHS to report to Congress by January 1, 1988, and every 3 years thereafter, on suicide among young people, including information on the causes and prevention of teenage suicide.

S. 2595 requires the Secretary to prepare for distribution television announcements on the health risks to women resulting from cigarette smoking.

The bill also amends the Federal Alcohol Administration Act to require the disclosure of alcohol content on labels of malt beverages.

Finally, S. 2595 amends title V of the PHS Act to require that alcoholic beverages display one of four health warning labels on a rotating basis and authorizes the Surgeon General to recommend additional labels on an annual basis.

II. Background and Need

The abuse of alcohol and drugs is one of the most serious problems facing this Nation. From 10 to 15 million Americans are either alcoholic or have serious problems directly related to the abuse of alcohol. Up to 35 million more are estimated to be affected indirectly as family members or other victims. Alcohol plays a role in 10 percent of all deaths in the United States. In some segments of the population, it produces even higher rates of mortality. It is the principal cause of accidental deaths among those aged 15 to 24.

Alcohol abuse during pregnancy has been found to cause fetal alcohol syndrome and other alcohol-related birth defects. In adults, alcohol abuse is the leading cause of cirrhosis of the liver (the eighth leading cause of death in the U.S.), the leading contributing factor of chronic pancreatitis, and has been implicated in a wide range of other diseases as well.

The picture regarding drug abuse is no less disheartening. In the U.S. today, more than 20 million persons use marijuana at least once a month. One of 20 high school seniors uses marijuana daily. Over four million persons, half of them between the ages of 18 and 25, are cocaine users. Approximately one-half million Americans are heroin addicts. Others are affected by significant problems of abuse involving medical drugs manufactured illicitly or diverted from legal sources.

Drug abuse leads to a variety of social and health problems. Excessive doses of depressants can result in both physical and psychological dependence. The toll from heroin addiction includes premature death or severe disability, family disruption, crime committed to maintain the habit, and an increased risk of contracting A.I.D.S.

Abuse of cocaine and dependence it fosters has become a serious, well-publicized problem affecting all aspects of an abuser's life, from marriage and family relationships to employment disruptions.

The economic, social, and human costs of substance abuse are devastating to our society. The costs in lost employment, reduced productivity, as well as health care, crime, motor vehicle accidents, and excess morbidity and mortality have been estimated at $116.7 billion annually for alcohol abuse and $59.7 billion for drug abuse.

It has been within the past two decades only that the Congress and the Federal Government have paid serious attention to the problems of substance abuse and have attempted to learn more about the causes of alcohol and drug abuse and how to prevent and treat it.

Prior to the late 1960s and the early 1970s, with a few notable exceptions, substance abuse had been generally ignored by all levels of government. The major source of assistance for those with alcohol abuse problems was the private voluntary sector, and a small number of private treatment clinics. By 1967, however, alcoholism had been recognized as a disease by the World Health Organization, the American Medical Association, the American Hospital Association, and the American Psychiatric Association. In addition, several Federal court cases had held that alcoholism in an illness or disease. During the late 1960s the alarmingly high incidence of alcoholism had also begun to be recognized by health officials.

The initial response of the Congress was passage of the District of Columbia Alcoholic Rehabilitation Act of 1967 (P.L. 90-452) which directed the establishment of a system for treating the illness of the alcoholic rather than condemning him to the "revolving door" of arrest, incarceration, release, and re-arrest. This approach was then applied nationally through the Alcoholic Rehabilitation Act of 1968 (P.L. 90-574) and the Community Mental Health Centers Amendments of 1970 (P.L. 91-211).

The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (P.L. 91-616) created NIAAA, and authorized a 3-year program of formula grants to the States, and contracts and projects grants, all aimed at the prevention and treatment of alcohol abuse and alcoholism. The 1974 amendments to P.L. 91-616 (P.L. 93-282) removed NIAAA from NIMH, locating it in the newly-created ADAMHA, and directed the Secretary of Health, Education, and Welfare (HEW), through NIAAA, to coordinate the efforts of other Federal agencies and Federally-supported programs. The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1976 (P.L. 94-371) extended the program of formula grants to the States for 3-years, and, in addition, added a new title specifically authorizing an extended research program by NIAAA, including authority for intramural research, and new authorization for the creation of national alcohol research centers.

The 1979 amendments to the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation legislation (P.L. 96-180) extended the program through FY 1981. In addition, concern over fetal abnormalities in infants born to certain mothers who consume alcoholic beverages, as well as other health hazards, and interest in health warning labels on alcohol beverage contain-

ers, prompted the requirement in P.L. 96-180 of a report to be conducted jointly by the Department of the Treasury, and the Department of Health, Education and Welfare. This report was to consider the extent and nature of birth defects associated with alcohol consumption by pregnant women, other health hazards associated with alcoholic beverages, and actions which should be taken by Federal agencies with respect to informing the general public of such hazards.

The Report acknowledged the enormity and range of health and safety problems associated with alcohol consumption, and indicated an alarmingly low level of consumer awareness regarding specific risks and medical conditions. The Report addressed the importance of public education on such alcohol-related phenomena as fetal alcohol syndrome/effects, drinking and cancer, and alcohol consumption with any of a wide range of drugs. Many of the federal and private sector strategies recommended in the Report to meet this public education need have not been implemented.

The Federal response to drug abuse problems in the U.S. closely paralleled the effort against alcohol abuse and alcoholism. The Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255) was enacted to "focus the comprehensive resources of the Federal government and bring them to bear on drug abuse with the immediate objective of significantly reducing the incidence of drug abuse in the United States within the shortest possible period of time, and to develop a comprehensive, coordinated long-term Federal strategy to combat drug abuse." In addition to establishing a Special Action Office for Drug Abuse Prevention (SAODAP) to provide overall planning and policy, P.L. 92-255 provided authority for an extended drug abuse prevention and treatment program, establishing NIDA within NIMH. This included formula grants to the States as well as special project grants and contracts for drug abuse treatment and prevention programs. In 1974, P.L. 93-282 removed NIDA from NIMH and located the agency in the newly-created ADAMHA.

The 1976 amendments to the original 1972 act (P.L. 94-237) made several changes in the drug abuse program. The 1976 legislation established the Office of Drug Abuse Policy (ODAP) within the Executive Office of the President. SAODAP's drug abuse programmatic responsibilities were transferred to NIDA, and the authority and role of the Secretary of HEW and the Director of NIDA were clarified. The authorizations of appropriations for State formula grants and project grants and contracts were extended for 3 years, through FY 1978. The 1978 amendments (P.L. 95-461) provided a 1-year extension.

The Drug Abuse Prevention, Treatment, and Rehabilitation Amendments of 1979 (P.L. 96-181) formalized the drug abuse coordination functions being carried out by the White House domestic policy staff, which was the successor to ODAP. It also extended authority for Federal drug abuse programs through FY 1981. It required preferential treatment of applications for project grants and contracts aimed at the drug problems of women, the elderly and youth under the age of 18.

In the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35) the Congress redefined the focus of Federal and State efforts in the

alcohol abuse, alcoholism, and drug abuse fields by providing for the creation of an Alcohol, Drug Abuse, and Mental Health Block Grant for distribution of alcohol and drug abuse program dollars which had previously been channeled via State formula grants and project grants and contracts. This approach was predicated on the belief that States should have increased authority and flexibility to plan, develop, and implement alcohol and drug abuse prevention, treatment, and rehabilitation programs appropriate to serve their respective populations. The block grant provided that of the money each State received for alcohol and drug abuse services at least 35 percent would be used for drug abuse services and at least 35 percent for alcoholism and alcohol abuse services. In addition, the Congress demonstrated its concern for the continuation of prevention programs by requiring that States earmark 20 percent of the block grant funds available to them for alcohol and drug abuse services for prevention and early intervention programs and services.

P.L. 97-35 also set continuing Federal priorities in this field by extending the authorizations of NIAAA and NIDA for an additional year to carry on high quality research and prevention programming, as well as information dissemination, clinical training, and technical assistance to the States.

Enactment of the block grant in 1981 changed fundamentally the role of NIAAA and NIDA, making research and training an even more important part of their mission. Congress, recognizing this, enacted the Alcohol and Drug Abuse Amendments of 1983 (P.L. 98-24), consolidating Federal alcohol, drug abuse, and mental health research activities for the first time into a single title of the Public Health Service Act, title V. The technical revisions and consolidation of these authorities into one title reflected the Congress' support for maintaining ADAMHA and its research and education functions as a separate entity within the PHS. P.L. 98-24 also included a 2-year reauthorization of research activities sponsored by NIAAA and NIDA.

The Alcohol, Drug Abuse, and Mental Health Amendments of 1984 (P.L. 98-509) extended the research authorities for 2 more years, through FY 1986. The 1984 amendments also authorized the Secretary to make grants to support demonstration projects in alcohol abuse and drug abuse prevention, treatment, and rehabilitation.

P.L. 98-509 also provided for the preparation and distribution of television announcements to educate the public concerning the dangers resulting from the consumption of drugs and alcohol.

HEALTH WARNING LABELS ON ALCOHOLIC BEVERAGES AND ALCOHOL DISCLOSURE FOR MALT BEVERAGES

The Committee and the Executive Branch have deliberated on the issue of mandating health warning labels on alcoholic beverages for a number of years.

On January 31, 1978, the Senate Subcommittee on Alcoholism and Drug Abuse held a hearing on "Alcohol Labeling and Fetal Alcohol Syndrome." On September 21, 1982, this Subcommittee held hearings on alcohol consumption during pregnancy.

The summary recommendation of the report issued as a result of the Subcommittee hearings included a recommendation that health warning labels should be required for alcoholic beverages including beer, wine, and distilled spirits.

On May 7, 1979, the Senate agreed to a Thurmond amendment to S. 440, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act Amendments of 1979, requiring beverages containing more than 24 percent alcohol by volume to bear the following health label:

CAUTION: CONSUMPTION OF ALCOHOLIC BEVERAGES MAY BE HAZARDOUS TO YOUR HEALTH

"Health Hazards Associated with Alcohol and Methods to Inform the General Public of These Hazardous," the 1980 report mandated by the Congressional Conference agreement on S. 440 (P.L. 96–180), and prepared by the Departments of HEW and Treasury, stated: "While the public generally knows that alcohol abuse can cause serious health problems for the abuser and individuals who come in contact with him or her, the Departments [of HEW and Treasury] do not believe that the public is sufficiently aware of all of the specific short and long term effects of alcohol on the health and well-being of different individuals. The Departments believe that a heightened awareness of those specifics would contribute to a lessening of the health problems related to alcohol."

The report also found that "Numerous information gaps and substantial misinformation relating to alcohol use exist among the American public. People are unaware of . . . the nature of links between drinking and cancer or birth defects, and problems can arise if alcohol is consumed with any one of a wide range of drugs. People generally have very limited knowledge about alcoholism—what it is and what resources are available for counseling and treatment."

The report recommended a variety of public information strategies to inform the public about the health risks of alcoholic beverages. Although the Departments did not recommend the implementation of warning labels on alcoholic beverages in 1980, they did suggest that "if, in the future, it is clear that other methods of informing have not been adequate and there is evidence that warning labels could make a significant contribution to the public's understanding of alcohol hazards, Congress should consider a requirement of warning labels for selected alcohol-related risks."

It should also be noted that this report was accompanied by an unusual White House disclaimer which expressed clear disagreement with the reports rejection of the current need for health warning labels as a public information/education strategy to inform consumers of its health risks of alcohol use.

In May 14, 1986, through Advanced Data Bulletin #119, the National Center for Health Statistics found that Americans are less knowledgable about the effects of alcohol on health than they are about the effects of smoking. Only one-third of those surveyed knew that heavy alcohol use was associated with cancers of the throat and only 31 percent were aware of the link between heavy alcohol use and mouth cancer. A 1985 Health Promotion and Dis-

ease Prevention Survey found that only 57 percent of all Americans had heard of Fetal Alcohol Syndrome.

The 1980 report also recommended that Congress should amend the Federal Alcohol Administration Act to require malt beverages to be labeled to disclose the alcohol content as a percent of volume. The Departments were convinced that public awareness and understanding would be enhanced if the alcohol content were consistently and clearly indicated on all alcoholic beverages.

III. History of S. 2595, Including Hearings

On February 20, 1986, the Subcommittee on Children, Family, Drugs and Alcoholism of the Senate Committee on Labor and Human Resources held hearings to review legislative initiatives to reauthorize Federal research programs aimed at preventing substance abuse. The following individuals testified:

Donald Ian MacDonald, M.D., Acting Assistant Secretary for Health of the Department of HHS; Loran Archer, Acting Director of NIAAA; and Jerome Jaffe, M.D., Acting Director of NIDA.

Jose Szapocznik, M.D., Research Professor of Psychiatry and Director of the Spanish Family Guidance Center and the Miami World Health Organization Collaborating Center, Department of Psychiatry, University of Miami, Coral Gables, Florida; and Thomas F. Babor, M.D., Associate Professor, Department of Psychiatry, Associate Director, Alcohol Research Center, University of Connecticut School of Medicine, Farmington, Connecticut.

Testimony was also received from Americans for Substance Abuse Prevention (ASAP), the National Council of Alcoholism, Inc., the National Association of State Alcohol and Drug Abuse Directors, and the American Psychiatic Association.

On May 13, 1986, S. 2443, a bill to amend the Public Health Service to revise the authorities of, and redesignate, the ADAMHA, was introduced by Senator Dole for Senator Hawkins and Senator Hatch, and referred to the Committee on Labor and Human Resources.

On May 20, the Committee met in executive session and, after accepting a Thurmond, Hatch, Kennedy amendment to require health warning labels on alcoholic beverages, agreed unanimously to report S. 2443 to the Senate.

On June 24, 1986, a revised version of S. 2443 which incorporated committee agreed-to versions to the Committee's liquor labeling provision was introduced in the Senate as S. 2595. The Committee met in executive session on June 25, 1986 and unanimously agreed to report S. 2595 to the Senate.

IV. Committee Views

The problems associated with alcohol, drug abuse and mental illness have had a tremendous negative impact on our nation. Estimates indicate that the economic costs of these three problems during 1985 alone totaled over $249.2 billion in lost productivity, health costs and crime. These costs, however, do not begin to measure the personal suffering and family disintegration which result from these problems and negatively impact upon the fabric of our society. Alcohol is involved in 100,000 deaths annually in the

United States and is strongly associated with trauma and disability for persons under forty-four. About one-third of Americans have used an illegal substance. The devastating effects of substance abuse among America's youth, our nation's future leaders, are especially severe. Recent studies indicate that more children are beginning to drink alcoholic beverages at an earlier age, and today's children are facing increased pressure to drink. Of the 9–13 year old alcohol users, 14 percent use alcohol at least monthly. Approximately two-thirds of our young people have tried an illegal drug before they have graduated from high school.

Through the Alcohol, Drug, and Mental Health Administration, redesignated in this legislation as the National Institutes on Alcohol, Drugs, and Mental Health (NIADMH), this nation is beginning to achieve some success in confronting and resolving the problems associated with substance abuse. The national leadership role of the NIADMH is broad, encompassing but not limited to, the following five major functions: (1) basic and applied research on the problems, their causes, prevention and treatment thereof; (2) administration of the Alcohol, Drug and Mental Health Services Block Grant and the provision of technical assistance to the States and providers; (3) prevention and knowledge transfer functions that include increasing national public awareness of these problems, disseminating information, especially through their respective clearinghouses, educating, training, data collection/analysis and research dissemination activities; (4) the demonstration of new methods of treatment, screening and the prevention of individuals at risk and new and improved methods of disseminating information; and (5) the provision of national leadership in many other vital areas including objective assessments of service needs and resources, and the development of meaningful national plans and reports, exploration and appropriate service financing strategies and the initiation of effective and mutually beneficial federal/state and public/private partnerships.

AUTHORIZATION LEVELS

Recognizing the current need for fiscal restraints, the Committee believes that Federal dollars invested in treatment and prevention services represent cost-effective expenditures. Every dollar expended will allow for breakthroughs in knowledge that can lead to better lives for the millions of Americans who are addicted to alcohol or other drugs and can lead to enormous economic savings to the nation.

For fiscal year 1987, the Committee sets the authorization levels at $83 million for the National Institute on Drug Abuse (NIDA) and $69 million for the National Institute on Alcohol Abuse and Alcoholism (NIAAA). The Committee also recommends a five-year reauthorization with such sums as are necessary after the first year of funding. The Committee hopes that a five-year reauthorization authority will provide the Institutes with the opportunity for more far-sighted and long-range research and prevention efforts.

NAME CHANGE FOR ADAMHA

Currently NIDA, NIAAA, and NIMH represent the premiere substance abuse and mental health research and prevention efforts in this country. They provide leadership in these areas to our nation as well as to other countries around the world. Because of the Institutes' importance and leadership, the Committee recommends a title change for the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) which currently administers these Institutes. Under the Committee provision ADAMHA would become the National Institutes on Alcohol, Drugs, and Mental Health (NIADMH). This title redesignation would in no way change the current jurisdiction or function of ADAMHA. However, the Committee believes that the title redesignation and the 5-year reauthorization would provide the necessary authority and recognition would provide the necessary authority and reauthorization would provide the necessary authority and recognition for these Institutes currently under the jurisdiction of ADAMHA. This names revision reflects the Congress' support for maintaining NIADMH as a discrete and independent agency of the U.S. Public Health Service (Report No. 98-29, page 12).

The Committee wishes to strongly reiterate this view. The Committee continues to be impressed with the quality and excellence of the research supported by the Institutes. Alcoholism, alcohol abuse, drug abuse and mental illness are serious national problems. Research, information, dissemination, encouragement of investigations and demonstrations of new methods of treatment and prevention, and technical assistance to the States as directed by the Secretary, are integral functions of these Institutes. With respect to prevention, the Committee previously noted in a recent report on the Alcohol, and Drug abuse Amendments of 1983 (S. Rept. 98-29) the need for more prevention and research and other research activities.

The Committee believes that this title redesignation, which will be carried out by the Administrator, can be accomplished at a reasonable cost with a minimal burden to NIADMH.

TECHNICAL AMENDMENT

In an effort to recodify all functions of NIADMH under Title V of the PHS, the Committee transferred all mental health components currently existing in Title III to Title V. This is merely a recodification effort and in no way changes the authority of the National Institute on Mental Health or the other Institutes within NIADMH. Specifically, in this recodifying effort no new or additional advisory boards, councils or commissions are designated. Further it is not the intent to require redesignation of existing boards or councils except in the case where existing membership requirements are changed.

The Committee believes that the current requirements for the submission of annual reports is unrealistic and repetitive, and has redesignated the submission dates from annual to triennial.

New information is often not available on an annual basis. Therefore previous annual reports have, at times, simply reiterated previous research findings. The Committee believes that a three-

year reporting period is a more reasonable time frame in which significant results can be reported, analyzed, and replicated. Such a time frame also offers a significant savings in terms of scarce personnel and economic resources which are currently devoted to producing these reports on an annual basis. This provision would permit the use of resources in the implementation of other high priority activities and initiatives, such as research prevention and public education.

The Committee is greatly concerned that the suicide rate among young people has tripled in the last thirty years. Suicide is now the second leading cause for death among young people. More than 4,000 youths take their own lives annually, and another 400,000 attempt suicide each year.

The Committee's bill requires that the Secretary report to Congress on January 1, 1988, and triennially thereafter on the causes of suicide among individuals under the age of 21. The Committee also requires that the Secretary publish and disseminate information on the causes and the means of preventing suicide among young people. The Committee intends that these activities be carried out in coordination with the Secretary's Task Force on Youth Suicide and with the cooperation of NIDA, NIAAA, and NIMH.

The 1984 reauthorizing legislation for NIAAA and NIDA mandated that the Department of Health and Human Services develop a national plan to combat alcoholism for submission to Congress by October 1, 1985. When this committee report was filed, the Congress had not yet received this national plan. The Committee strongly reiterates that statutory target dates are not included in legislation frivolously. Failure by the Department to meet dates included in statute is viewed by the Committee with the utmost seriousness.

PUBLIC EMERGENCIES

In the event of a national public health emergency, the Committee requests that the Secretary expedite all essential research and prevention efforts through the in-place advisory councils and peer review groups. This provision will assure that future national health crises receive immediate consideration and not be tied up in bureaucratic red tape.

ANIMALS IN RESEARCH

The Committee bill seeks to codify regulatory restrictions currently applicable to NIH to address the concerns of a growing number of our citizens about the inhumane and unnecessary use of animals in research. The Committee does not intend that the language in Section 509(a) of this bill be interpreted to inhibit government investigations into allegations of improper care or use of laboratory animals. Such investigations may be required to assure compliance with the provisions of Section 509(a).

ADVISORY COUNCILS

The Committee intends that the Institutes not only promote and conduct essential and pertinent research but also publicize and dis-

seminate these efforts. To streamline these efforts, the Committee bill requires that nine of the twelve Advisory Council members be experts in either the health or scientific fields. To focus greater national visibility on research findings, the Committee feels that one member of the Council must be knowledgeable in the area of public relations. The Committee emphasizes that the changes in the makeup of the Advisory Council will be carried out by attrition when the individual terms expire.

CHILD ABUSE REPORTING

Section 6 of the Committee bill eliminates the prohibition on disclosure of information from alcohol and drug abuse patient records to permit the straight forward reporting of child abuse and neglect in accordance with State law. While Federal confidentiality law and regulations permit such reports in prescribed circumstances (i.e., pursuant to a special court order; if the report does not identify the patient as an alcohol or drug abuse patient; if the patient gives written consent; if a bona fide medical emergency exists; or in accordance with a qualified service organization agreement between the treatment program and the agency to which reports of child abuse must be made) the Committee intends to simplify such reporting by removing any barriers, actual or perceived, to disclosure of information from alcohol and drug abuse patient records for the purpose of reporting child abuse or neglect in accordance with State law.

The Committee affirms that this provision is in no way intended to raise a presumption that either parent or guardian should be reported or investigated for child abuse or neglect solely because they are participating in an alcohol or drug abuse treatment program. Rather, this provision merely permits the unincumbered reporting of abusive or neglectful acts or omissions which have an effect on or threaten the welfare of a child in accordance with State law.

The Committee affirms the right of persons seeking treatment for alcoholism and alcohol abuse and drug addiction and drug abuse to do so with the assurance that their records will be treated confidentially and does not intend that this provision diminish confidentiality protections for patients in alcohol and drug abuse programs which are federally conducted, regulated or assisted.

AUTHORITY TO UTILIZE VOLUNTEERS

The Committee bill makes explicit that NIADMH and the Institutes can utilize volunteers for purposes other than clinical care. The current authority covering the use of volunteers in Section 223 of the Public Health Service Act limits the use of volunteers to facility operations associated with clinical care.

Considering current budget limitations, the Committee believes that a wider utilization of volunteers is essential. Under this new authority, volunteers could work in research laboratories and other facilities which are not currently providing direct or ancillary clinical care. Such an authority offers the agency some additional flexibility in the use of volunteers at no Federal cost.

PUBLIC SERVICE ANNOUNCEMENTS

The Committee recognizes that one of our most pressing drug problems is tobacco addiction. In 1986, lung cancer will become the number one cause of cancer death in women. More than 41,000 women will die from lung cancer, and if current trends continue, one of every 33 women in this country will succumb to this preventable disease. Most of these deaths are directly caused by women smoking.

Women who smoke face special risks, especially during pregnancy. Smoking increases the risk of spontaneous abortion and neonatal deaths. Women who smoke are also more likely to have lower birth weight babies. In addition, women who smoke and are on birth control bills are much more likely to have strokes, high blood pressure and other complications. It is also now clear that smoking presents risk to others.

Therefore, this legislation requires the Secretary to prepare for distribution public service announcements on the health risks of smoking for women. In carrying out this requirement, the Committee expects that the National Institute on Drug Abuse (NIDA) will work closely with the Office of Smoking and Health in the development of these announcements. The Committee requires that $250,000 a year will be available for three years for these public service announcements.

ALCOHOL CONTENT LABELING

The Committee supports revisions in law to mandate the disclosure of the alcohol content of malt beverages on the labels of such beverages and permit advertising of such beverages to include alcohol content. The Committee, through this provision, endorses the findings of a 1980 Report to the President and Congress prepared by the Department of Treasury and the Department of Health and Human Services entitled "Health Hazards Associated with Alcohol and Methods to Inform the General Public of These Hazards." This report recommended that "Congress should amend the F.A.A. Act to require malt beverages to be labeled to disclose the alcohol content as a percent by volume." The Departments further stressed their findings that public awareness and understanding would be enhanced if the alcoholic content were consistently and clearly indicated on all domestic and imported alcoholic beverages. The consumer could then, at least, comparatively evaluate the products.

Therefore, the Committee, through the adoption of this amendment, supports this recommendation and assures consumers access to information which they want on the alcohol content of malt beverages. Furthermore, it encourages consumer responsibility in the use of malt beverages, and eliminates disparities between labeling requirements for malt beverages and high alcohol wines and distilled spirits.

In adopting this language, however, the Committee did not intend to permit irresponsible label statements or advertisements pertaining to alcohol content. The Committee language would retain the Secretary of Treasury's authority to prohibit such nonquantitative statements as "strong," "extra strong," "high test," or "high proof." What the Committee language would require is that

brewers of malt beverages label their containers with numerical information as follows: "—% alcohol by volume."

This label requirement would become effective one year after the date of enactment of this Act. During the one-year transition period between enactment and the effective date of this requirement, brewers would be authorized (but not required) to provide such numerical information on the labels of their malt beverage containers. The purpose of this transition period is to give the manufacturers of malt beverages a reasonable time to make the necessary label changes and get them implemented, while giving the Treasury Department time to promulgate needed revisions to the regulations to carry out this provision.

This Committee language would authorize (but not require) brewers to include numerical information on the percentage of alcohol content by volume in any advertisement of malt beverages. The discretion to include this type of information in advertisements would be conferred on malt beverage manufacturers; the Secretary would not be authorized to curtail or eliminate it.

The Secretary's authority and duty to prevent false or misleading labeling or advertising would not be abridged by the Committee's language. Likewise, the Committee intends that the Secretary retain pre-existing authority to control the manner of conveying this information on the labels and in advertising of malt beverages so as to prevent "pandering" or "bidding wars" based on the higher alcohol content of any malt beverage.

The Committee recognizes that the brewing of malt beverages is a biological process which is capable of being managed only within certain limits or ranges of variability. Quality control is not an exact science in this industry. Precision is impossible. Thus, it is recognized that each batch of malt beverage brewed may vary slightly from every other batch of the same malt beverage. It is the Committee's intent, therefore, that the Secretary's regulations to implement the alcohol content disclosure provision take this inevitable variability into account expressly.

The regulations should permit the brewer to state on the label a single number which reflects the percentage of alcohol by volume which is the approximate average for batches of the same beverage which fall within the normal range of product variability. The brewer should not be required to vary the label for each production batch so long as reasonably available quality controls are employed and the label presents a generally accurate indicator of the average alcohol content by volume of that brand of malt beverage.

ALCOHOL WARNING LABEL

The Committee favorably approved an amendment to require rotating warning labels on alcoholic beverages to facilitate a national public education effort to make our citizens more aware of the health consequences of abusing alcoholic beverages. This amendment would require the manufacturers of beer, wine and liquor to place in a conspicuous and prominent place on the container a label bearing one of four warning statements, to be randomly displayed during each twelve month period in as equal a number of times as is possible on each brand of the beverage and be randomly

distributed in all parts of the United States in which the brand is marketed: The required labels include:

"Warning: The Surgeon General has determined that the consumption of this product, which contains alcohol, during pregnancy may cause birth defects."

"Warning: Drinking this product, which contains alcohol, can impair your ability to drive a car or operate heavy machinery."

"Warning: This product contains alcohol and is particularly hazardous in combination with some drugs."

"Warnings: The consumption of this product, which contains alcohol, can increase the risk of developing hypertension, liver disease and cancer."

In addition, S. 2595 provides that the Surgeon General recommend one additional warning label if deemed necessary to further educate our nation's consumer on the hazards of alcohol abuse. It is not the intention of the Committee that the Surgeon General produce additional labels if none are appropriate.

S. 2595 will require that health warning labels be placed on all alcoholic beverages—distilled spirits, beer and wine. This action follows previous Committee decisions to require health warning labels on other products which pose risks to the consumer such as cigarettes and smokeless tobacco. Other products which bear health warning labels include: over-the-counter drugs, prescriptions medications, aspirin, and products containing saccharin. Therefore, beverages with alcohol will no longer be exempt from a key consumer information strategy. The legislation also provides that a violation of this labeling requirement would be a misdemeanor punishable by a fine of not more than $10,000.

The Committee does not deem this legislation as regulatory, nor proscriptive of our citizens' right to drink alcoholic beverages, but simply as an appropriate and necessary Federal effort to provide for public education. The Committee considers this measure an important part of the ongoing effort in disease prevention and health promotion which is among the highest priorities of our national health policy.

Numerous studies indicate that the public is not sufficiently aware of all the short- and long-term effects of alcohol abuse, and misuse, on their health and well-being. The 1980 Report to the President and Congress from the Departments of Treasury and Health and Human Services indicated that a "heightened awareness of these specifics would contribute to a lessening of the health problems related to alcohol."

S. 2595 also provides that alcoholic beverages intended for foreign consumption would be exempt from the labeling requirement, except that beverages intended for consumption by members of the U.S. Armed Forces outside the U.S. would not be exempt.

Finally, the Committee wants to emphasize that, by including provisions in S. 2595 which requires health warnings on alcoholic beverage containers for alcoholic beverages, and by preempting State and local laws requiring additional health warnings, it does not intend to preempt a State's ability to control the promotion or advertising of alcoholic beverage products and does not intend to preempt product liability suits in State or Federal courts based on failure to warn.

V. Votes in Committee

The Committee unanimously reported S. 2595 without amendments.

VI. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, June 4, 1986.

Hon. Orrin G. Hatch,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for S. 2595, the Alcohol, Drug Abuse, and Mental Health Amendments of 1986, as ordered reported by the Senate Committee on Labor and Human Resources on May 21, 1986.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes,

Sincerely,

Rudolph G. Penner.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 2595.
2. Bill title: Alcohol, Drug Abuse, and Mental Health Amendments of 1986.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on May 21, 1986.
4. Bill purpose: To revise the authorities of, and redesignate, the Alcohol, Drug Abuse, and Mental Health Administration.
5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1987	1988	1989	1990	1991
Estimated authorization levels:					
Alcohol abuse and alcohol research	69.0	73.0	77.0	82.0	86.0
Drug abuse research	83.0	88.0	93.0	98.0	104.0
Teen suicide	0.5	0.5	0.5	0.6	0.6
Total estimated authorization level	152.5	161.5	170.5	180.6	190.6
Estimated outlays:					
Alcohol abuse and alcohol research	48.0	64.0	72.0	79.0	84.0
Drug abuse research	58.0	77.0	87.0	94.0	101.0
Teen suicide	0.5	0.5	0.5	0.6	0.6
Total estimated outlays	106.5	141.5	159.5	173.6	185.6

The costs of this bill fall within budget function 550.

Basis of estimate: We assume all authorized amounts are fully appropriated at the beginning of each fiscal year. Outlays are estimated by CBO on the basis of recent program data. All authorizations are subject to subsequent appropriations actions.

Sections 2 through 9 of this bill would amend the Public Health Service Act to redesignate the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) as the National Institutes on Alcohol, Drugs, and Mental Health and would reauthorize the activities of the Institutes.

Sections 2 and 3 of the bill redesignating ADAMHA and providing for advisory councils would more specifically codify activities currently carried out by ADAMHA, resulting in no additional cost to the federal government. Section 4 of the bill would allow expedited review of grant applications for research dealing with diseases or disorders determined to be public health emergencies. This section is not expected to result in additional cost to the federal government.

The authorization levels for alcohol and drug abuse research are stated in section 5 of the bill for fiscal year 1987. The bill authorizes such sums as may be necessary for research in 1988 through 1991. Authorization levels for these years were estimated by increasing the 1987 stated amounts by the projected rate of inflation for health research.

Section 6 of the bill would clarify current law dealing with the confidentiality of patient records so as not to prohibit the reporting of suspected child abuse and neglect. This provision is expected to result in no additional cost to the federal government.

Section 7 of the bill would authorize the Secretary of Health and Human Services to develop and publish information on the causes and prevention of teen suicide. No specific authorization for appropriations is stated in the bill. Based on similar information collection and dissemination activities within the federal government, CBO has estimated the cost of this provision to be between $500,000 and $600,000 in each fiscal year. Costs could be higher or lower depending on the actual level of activity undertaken.

Guidelines for the care of animals used in research would be specifically written into law by section 8 of the bill. Animal care committees would be required at each research entity receiving funds under this title. According to ADAMHA, such animal care committees and guidelines are already in place.

Enactment of this provision would result in no additional cost to the federal government.

Public service announcements would be authorized by section 9 of the bill to educate the public concerning the dangers of cigarette smoking for women; $250,000 of the funds ultimately appropriated under section 5 of the bill would be authorized for this activity.

Section 10 of this bill would amend the Federal Alcohol Administration Act to require labels on bottles of malt beverages to bear accurate statements of the alcoholic content of those beverages. Under current law, such statement of alcoholic content are prohibited, unless required by state law. Section 10 would also require the Secretary of the Treasury to revise the relevant regulations to reflect these amendments. CBO expects these amendments to result in no significant cost to the federal government.

Section 11 of the bill would again amend the Public Health Service Act to require all alocholic beverage containers to bear one of four specific warning labels concerning the health hazards associat-

ed with alcoholic beverages. None of the costs associated with container labeling would be borne by the federal government.

6. Estimated cost to state and local government: The budgets of state and local governments would not be affected directly by the enactment of this bill.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Carmela Dyer.

10. Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

VII. Regulatory Impact Statement

The Committee has determined that there will be a minimal increase in the regulatory burden or paperwork imposed by this bill. There will, in fact, be a reduction in federal requirements by requiring that the current annual prevention report be submitted every three years. Furthermore, the Secretary is obligated to report to Congress on January 1, 1988, and every three years thereafter, on the trends, causes and prevention strategies for suicide among young people. The legislation does require that the name for the current Alcohol, Drug Abuse, and Mental Health Administration be changed which will require eventual modifications in facility signs, stationery, and publications.

VIII. Family Fairness Statement

The Committee, through the reauthorization of our nation's premiere research institutes on drug and alcohol abuse, realizes the significant familial problems and solutions associated with substance abuse. This legislation would require that public service announcements be prepared on the health effects of nicotine on women—specifically mothers who smoke in the home with small children. Also, this legislation would ask the Secretary to submit a triannual report on the nature of suicide among young people in America. Finally, the Committee supported two provisions which would seek to educate all family members on alcohol use. One provision would require all malt beverages to note the level of alcohol content. Another provision would require that four health warning labels be rotated on all alcoholic beverages. The Committee encourages familial involvement in the delivery of alcohol, drug abuse and mental health services. Statistics show that familial involvement increases the success of the treatment.

IX. Section-by-Section Analysis

The bill provides that the act may be cited as the "Alcohol, Drug Abuse, and Mental Health Amendments of 1986."

Section 2(a) of the bill amends section 501 of the PHS Act to revise and redesignate ADAMHA as NIADMH. Section 501(a) as revised establishes NIADMH as an agency of the PHS. Section 501(b) as revised states that the three research institutes, NIAAA, NIDA, and the National Institute of Mental Health (NIMH) are agencies of NIADMH, and that, for the purposes of title V, the

term "national research institute" refers to these institutes and a reference to NIADMH includes these institutes.

Section 501(c) as revised provides that NIADMH shall be headed by an Administrator appointed by the President with the advice and consent of the Senate, and that the Administrator, with the approval of the Secretary of HHS, may appoint a Deputy Administrator and employ necessary officers and employees.

Section 501(d) as revised requires the Secretary, acting through the Administrator to: (1) supervise the functions of the three research institutes to assure that the programs that each institute carries out receive appropriate and equitable support and that there is cooperation among the three institutes in implementing such programs; and (2) assure that the research at or supported by NIADMH and each of the institutes is subject to review in accordance with peer review procedures described in section 507 and is in compliance with guidelines regarding the use of animals in research as established under section 509 created by this bill.

Section 501(e)(1) as revised provides for the establishment in NIADMH of an Associate Administrator for Prevention and describes the duties of this position. Section 501(e)(2) as revised requires the Secretary, acting through the Associate Administrator for Prevention, to submit, by January 1, 1988, and every 3 years thereafter, a report to Congress describing prevention activities undertaken by NIADMH and the three research institutes, including a detailed statement of expenditures made for, and personnel used in connection with, such activities.

Section 501(f) as revised requires the Administrator to establish a process for responding to information on scientific fraud and violations of the rights of human subjects in connection with research for which funds have been made available under this act.

Section 501(g) as revised authorizes grants to schools of the health professions and of social work to support student training in the identification and treatment of alcohol and drug abuse.

Section 501(h) as revised authorizes the Administrator to take necessary actions to ensure the widespread dissemination of publications of NIAAA and NIDA to educate the public on the health hazards of alcoholism, alcohol abuse, and drug abuse.

Section 501(i) as revised authorizes the Administrator to obtain the services of not more than 20 experts or consultants with scientific or professional qualifications. Experts and consultants shall be obtained for NIADMH and each of the three research institutes. They shall be paid or reimbursed for certain expenses, but only if they agree to complete the entire period of assignment or 1 year, whichever is shorter.

Section 501(j) as revised authorizes the Administrator to accept voluntary and uncompensated services for NIADMH and for each of the three institutes.

Section 501(k) as revised provides for the establishment and operations of the Alcohol, Drug Abuse, and Mental Health Advisory Board.

Section 2(b) of S. 2443 amends the title heading for title V of the PHS Act to read: "National Institutes on Alcohol, Drugs, and Mental Health", and the title of Part A to read "Administration."

Section 2(c) of the bill redesignates ADAMHA as NIADMH and the Administrator or officials of ADAMHA as Administrator or officials of NIADMH and provides that any reference to ADAMHA or its Administrator or officials in any law, rule, regulation, certificate, directive, instruction, or other official paper in force at the time of enactment of this act shall be deemed to refer and apply to NIADMH or its Administrator or official.

Section 3(a) of the bill redesignates sections 505 and 506 of the PHS Act as sections 506 and 507, and inserts a new section 505, "Advisory Councils."

Subsection (a) of the new section 505 reiterates the present authority of the Secretary to appoint advisory councils for each of the three research institutes in NIADMH. Each advisory council would advise, consult with, and make recommendations to the Secretary and the Director of the institute for which it was appointed on matters and policies relating to activities carried out by and through the institute and matters relating to activities carried out by the Secretary and by NIADMH concerning the disease, disorder, or other aspect of human health with which the advisory council is concerned.

Each advisory council may recommend to the Secretary acceptance of conditional gifts for: (A) study, investigations, or research; (B) the acquisition of grounds for the institute; or (C) the construction, equipping, or maintenance of facilities for the institute.

Each advisory council may make recommendations to the Director of the institute concerning research conducted at the institute, shall review applications for grants and cooperative agreements for research and training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute.

Each advisory council may collect information on stuties being carried on in the U.S. or elsewhere on the diseases, disorders, or other aspect of human health with which its research institute is concerned and, with the Director's approval, make such information available through appropriate publication for the benefit of public and private health entities and health professions personnel and scientists, and for the information of the public. Each advisory council may appoint subcommittees and convene workshops and conferences.

Subsection (b) of the new section 505 describes the makeup and membership of the advisory councils. Each such council will include such ex officio members as the Secretary of HHS, the Administrator of NIADMH, the Director of the respective research institute, the Chief Medical Director of the Veterans Administration, the Assistant Secretary of Defense for Health,or their designees, and other officers and employees of the U.S. as the Secretary determines necessary, and not more than twelve members appointed by the Secretary. Nine of the public members shall be appointed from among leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the research institute for which the advisory council is established, and three members shall be ap-

pointed from the general public and shall include letters infields of public policy, public relations, law, health policy, economics, and management.

Subsection (c) of section 505 provides that the term of office of an appointed member of an advisory council is 4 years, except that appointments will be made so that the terms of members do not all expire in the same year.

Subsection (d) provides that the chairman of an advisory council shall be selected by the Secretary from the among the appointed members, except that the Secretary may select the Director of the respective research institute to be chairman of the advisory council.

Subsection (e) provides that an advisory council shall meet at the call of the chairman or upon request of the research institute, but at least three times each fiscal year.

Subsection (f) of section 505 provides for the designation of a staff member of a research institute to be executive secretary of its advisory council. In addition, the Director of an institute will make available to its advisory council such staff, information, and other assistance as it may require to carry out its function. The Director shall also provide orientation and training for new advisory council members to provide them with appropriate information and training for their effective participation in the function of the council.

Section 3(b) of the bill amends section 217 of the PHS Act to strike references to the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, and the National Council on Drug Abuse.

Section 4 of the bill amends title V of the PHS Act by adding a new section 508, "Research on Public Health Emergencies." The new section 508(a) authorizes the Secretary, after a determination, reached in consultation with the Administrator of NIADMH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control, that a disease or disorder within the jurisdiction of one of the research institutes constitutes a public health emergency, to take certain actions. Acting through the Administrator of NIADMH, the Secretary: (1) shall expedite the review by advisory councils and peer review groups of applications for grants or contract proposals for research on such disease or disorder; (2) shall exercise the authority in section 3709 of the Revised Statutes respecting public exigencies to waive the advertising requirements concerning proposals for contracts for such research; (3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; or (4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatement of such disease and disorder that is developed in research assisted under this section.

The amount of an increase in a grant or contract provided for this section may not exceed one-half of the original grant or contract amount.

The new section 508(b) requires the Secretary to report to the House Committee on Energy and Commerce and the Senate Committee on Labor and Human Resources not later than 90 days after

the end of a fiscal year on actions taken under this section during the fiscal year.

Section 5(a) of the bill amends section 513 of the PHS Act to authorize appropriations of $69 million for FY 1987 and such sums as may be necessary for FY 1988 through FY 1991 for research on alcohol abuse and alcoholism. Section 5(b) amends section 517 of the PHS Act to authorize appropriations of $83 million for FY 1987 and such sums as may be necessary for FY 1988 through FY 1991 for drug abuse research.

Section 6 of the bill amends sections 523 and 527 of the PHS Act, concerning confidentiality of patients records maintained in connection with Federally-assisted alcohol abuse and drug abuse programs respectively. These sections are amended to provide that prohibitions against disclosure of records of patients in such programs do not apply to the reporting under State law of incidents of suspected child abuse and neglect to appropriate State authorities.

Section 7 of the bill amends section 501 of the PHS Act to add a new subsection (k) requiring the Secretary to develop and publish information on the causes of suicide among persons under age 21 and the means of preventing such suicides and to make such information generally available to the public and to health professionals. In addition, the new section 501(k) requires the Secretary to report to Congress by Janaury 1, 1988, and every 3 years thereafter, on the activities undertaken in this area and an assessment of the effectiveness of such activities.

Section 8 of the bill amends title V of the PHS Act by adding a new section 509, "Animals in Research." The new section 509(a) requires the Secretary, acting through the Administrator of NIADMH, to establish guidelines for the proper care and treatment of animals in research conducted by and through agencies of NIADMH. Such guidelines must require the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia, and the appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research. Such guidelines shall not be construed to prescribe the methods of research.

The new section 509(b) directs the Secretary to establish guidelines requiring animal care committees at each entity which donducts research with funds under title V to assure compliance with guidelines for animal care and treatment. Each animal care committee would be appointed by the chief executive officer of the entity for which it is established, would be composed of not fewer than three members, and include at least one individual with no association with the research entity and at least one doctor of veterinary medicine. Each animal care committee of an entity would review the care and treatment of animals in all animal study areas and facilities of the research entity at least semiannually to evaluate compliance with applicable guidelines, keep appropriate records of reviews, and for each review file with the Administrator of NIADMH at least annually a certification that the review has been conducted and reports of violations. Such reports must include any minority views filed by committee members.

The new section 509(c) authorizes the Administrator to require each applicant for a grant, contract, or cooperative agreement involving research on animals to include in its applications or con-

tract proposal, assurances that the applicant meets requirements concerning animal care guidelines and has an animal care committee, and that scientists, animal technicans, and other personnel involved with animal care, treatment, or use have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit animal use or limit animal stress. Research applications and contract proposals must also include a statement of the reasons for the use of animals in the research to be conducted with funds under the grant or contract.

The new section 509(d) authorizes the Administrator to suspend or revoke the grant or contract to an entity if the Administrator determines that: (1) the conditions of animal care, treatment, or use in that entity do not meet guidelines established under this section; (2) the entity has been notified of such determination and has been given a reasonable opportunity to take corrective action; and (3) no corrective action has been taken.

The new section 509(e) provides that no guidelines or regulation promulgated under this section may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.

Section 9 of the bill amends section 503 of the PHS Act to require the Secretary, acting through NIDA and the Office on Smoking and Health, to prepare for distribution announcements for television to educate the public, particularly women, concerning the dangers resulting from cigarette smoking. In preparing such announcements, the Secretary shall, to the extent feasible, use appropriate private organizations and business concerns. The section provides that $250,000 of the amounts appropriated for drug abuse research each year for FY 1987 through FY 1989 shall be available to prepare these announcements.

Section 10 of the bill amends the Federal Alcohol Administration Act to require alcohol content disclosure on labels of malt beverages.

Section 11 of the bill adds a new section 531 to the PHS Act making it unlawful to manufacture, import, distribute, sell, ship, package, or deliver for sale or distribution in the U.S. any alcoholic beverage unless the container bears one of four warning statements. The required label would have to be located in a conspicuous and prominent place on the container, and in conspicuous and legible type. Each of the four statements would have to be randomly displayed in each 12-month period in as equal a number of times as is possible on each brand of the beverage and be randomly distributed in all parts of the U.S. in which the brand is marketed. A fifth warning label may be added by the Surgeon General on the recommendation of NIAAA. Violation of this labeling requirement would be misdemeanor punishable by the fine of not more than $10,000.

Alcoholic beverages intended for foreign consumption would be exempt from the labeling requirement, except that beverages intended for consumption by members of U.S. Armed Forces outside the U.S. would not be exempt.

Nothing in the new section 531 should be construed to relieve any person from any liability under Federal or State law to any other person.

For this section, "alcoholic beverage" includes distilled spirits, wine, and malt beverages.

Section 12 of the bill makes a technical amendment to section 504(e)(2)(A) of the PHS Act.

X. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

* * * * * * *

NATIONAL ADVISORY COUNCILS

Sec. 217. [(a) The National Advisory Mental Health Council and the National Advisory Council on Alcohol Abuse and Alcoholism shall each consist of the Surgeon General, who shall be chairman, the chief medical officer of the Veterans' Administration or his representative and a medical officer designated by the Secretary of Defense, who shall be ex officio members; and twelve members appointed without regard to the civil service laws by the Secretary. The twelve appointed members of each such council shall be leaders in the fields of fundamental sciences, medical sciences, or public affairs, and six of such twelve shall be selected from among the leading medical or scientific authorities who, in the case of the National Advisory Mental Health Council and the National Advisory Council on Alcohol Abuse and Alcoholism, are outstanding in the study, diagnosis, or treatment of psychiatric disorders and alcohol abuse and alcoholism, respectively. In the case of the National Advisory Council on Alcohol Abuse and Alcoholism, the Secretary shall assure that its membership is broadly representative of experts in the fields of prevention, research, and treatment of alcohol abuse, alcoholism, and rehabilitation of alcohol abusers. Each appointed member of each such council shall hold office for a term of four years, except that (1) any member appointed to fill a vacancy occurring prior to the expiration of the terms for which his predecessor was appointed shall be appointed for the remainder of such term; (2) the terms of the members (other than the members of the National Advisory Council on Alcohol Abuse and Alcoholism) first taking office after September 30, 1950, shall expire as follows: Three shall expire four years after such date, three shall expire three years after such date, three shall expire two years after such date, and three shall expire one year after such date, as designated by the Surgeon General at the time of appointment; and (3) the terms of the members of the National Council on Alcohol Abuse and Alcoholism first taking office after the date of enactment of

this clause, shall exprie as follows: Three shall expire four years after such date, three shall expire three years after such date, three shall expire two years after such date, and three shall expire one year after such date, as designated by the Secretary at the time of appointment. None of the appointed members shall be eligible for reappointment within one year after the end of his preceding term, but terms expiring prior to October 1, 1950, shall not be deemed "preceding terms" for the purposes of this sentence.

[(b) The National Advisory Mental Health Council shall advise, consult with, and make recommendations to the Surgeon General on matters relating to the activities and functions of the Service in the field of mental health. The Council is authorized (1) to review research projects or programs submitted to or initiated by it in the field of mental health and recommend to the Surgeon General, for prosecution under this Act, any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of psychiatric disorders; and (2) to collect information as to studies being carried on in the field of mental health and, with the approval of the Surgeon General, make available such information through the appropriate publications for the benefit of health and welfare agenices or organizations (public and private), physicians, or any other scientists, and for the information of the general public. The council is also authorized to recommend to the Surgeon General, for acceptance pursuant to section 2101 of this Act, conditional gifts for work in the field of mental health; and the Surgeon General shall recommend acceptance of any such gifts only after consultation with the Council.

[(c) The National Advisory Council on Alcohol Abuse and Alcoholism shall advise, consult with, and make recommendations to, the Secretary on matters relating to the activities and functions of the Secretary in the field of alcohol abuse and alcoholism, including policies and priorities with respect to grants and contracts. The Council is authorized (1) to review research projects or programs submitted to or initiated by it in the field of alcohol abuse and alcoholism and recommended to the Secretary any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of alcohol abuse and alcoholism, and (2) to collect information as to studies being carried on in the field of alcohol abuse and alcoholism and, with the approval of the Secretary, make available such information through appropriate publications for the benefit of health and welfare agencies or organizations (public or private) or physicians or any other scientists, and for the information of the general public. The Council is also authorized to recommend to the Secretary, for acceptance pursuant to section 2101 of this Act, conditional gifts for work in the field of alcohol abuse and alcoholism; and the Secretary shall recommend acceptance of any such gifts only after consultation with the Council.

[(d)(1) The National Advisory Council on Drug Abuse shall consist of the Secretary, who shall be Chairman, the chief medical officer of the Veterans' Administration or his representative, and a medical officer designated by the Secretary of Defense, who shall

be ex officio members. In addition, the Council shall be composed of twelve members appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service. The appointed members of the Council shall represent a broad range of interests, disciplines, and expertise in the drug area and shall be selected from outstanding professionals and paraprofessionals in the fields of medicine, education, science, the social sciences, and other related disciplines, who have been active in the areas of drug abuse prevention, treatment, rehabilitation, training, or research.

[(2) The Council shall advise, consult with, and make recommendations to, the Secretary—

[(A) concerning matters relating to the activities and functions of the Secretary in the field of drug abuse, including, but not limited to, the development of new programs and priorities, the efficient administration of programs, and the supplying of needed scientific and statistical data and program information to professionals, paraprofessionals, and the general public; and

[(B) concerning policies and priorities respecting grants and contracts in the field of drug abuse.

[(e)(1)] *(a)* Within 120 days of the date of the enactment of this subsection, the Secretary shall appoint and organize a National Advisory Council on Migrant Health (hereinafter in this subsection referred to as the Council) which shall advise, consult with, and make recommendations to, the Secretary on matters concerning the organization, operation, selection, and funding of migrant health centers and other entities under grants and contracts under section 329.

[(2)] *(b)* The Council shall consist of fifteen members, at least twelve of whom shall be members of the governing boards of migrant health centers or other entities assisted under section 329. Of such twelve members who are members of such governing boards, at least nine shall be chosen from among those members of such governing boards who are being served by such centers of grantees and who are familiar with the delivery of health care to migratory agricultural workers and seasonal agricultural workers. The remaining three Council members shall be individuals qualified by training and experience in the medical sciences or in the administration of health programs.

[(3)] *(c)* Each member of the Council shall hold office for a term of four years, except that

[(A)] *(1)* any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

[(B)] *(2)* the terms of the members first taking office after the date of enactment of this subsection shall expire as follows: four shall expire four years after such date, four shall expire three years after such date, four shall expire two years after such date, and three shall expire one year after such date, as designated by the Secretary at the time of appointment.

[(4)] *(d)* Section 14(a) of the Federal Advisory Committee Act shall not apply to the Council.

* * * * * * *

TITLE V—[ADMINISTRATION AND COORDINATION OF THE NATIONAL INSTITUTE OF MENTAL HEALTH, THE NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM, AND THE NATIONAL INSTITUTE ON DRUG ABUSE] *NATIONAL INSTITUTES ON ALCOHOL, DRUGS, AND MENTAL HEALTH*

[PART A—ADMINISTRATION AND INSTITUTES]

PART A—ORGANIZATION

[ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION]

[SEC. 501. (a) The Secretary shall establish, in the Department, the Alcohol, Drug Abuse, and Mental Health Administration (hereinafter in this section referred to as the "Administration"). The Administration shall be headed by an Administrator appointed by the President, by and with the advice and consent of the Senate. The Administrator, with the approval of the Secretary, may appoint a Deputy Administrator and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.

[(b) The Secretary, acting through the Administration, shall supervise the functions of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse in order to assure that (1) the programs carried out through each such Institute receive appropriate and equitable support, and (2) there is cooperation among the Institutes in the implementation of such programs.

[(c)(1) There is established the Alcohol, Drug Abuse, and Mental Health Advisory Board (hereinafter in this subsection referred to as the "Board"). The Board shall—

[(A) periodically assess the national needs for alcoholism, alcohol, abuse, drug abuse, and mental health services and the extent to which those needs are being met by State, local, and private programs and programs receiving funds under this title and part B of title XIX, and

[(B) provide advice to the Secretary and the Administrator respecting activities carried out under this title and part B of title XIX.

[(2)(A) The Board shall consist of fifteen members appointed by the Secretary and such ex officio members from the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health as the Secretary may designate. Of the members appointed to the Board, at least six members shall represent State and private, nonprofit, providers of prevention and treatment services for alcoholism, alcohol abuse, drug abuse, and mental illness, at least six members shall be individuals with expertise in public education and preven-

tion services for alcoholism, alcohol abuse, drug abuse, and mental illness, and at least three members shall be appointed from members of the general public who are knowledgeable about alcoholism, alcohol abuse, drug abuse, and mental illness.

[(B) The term of office of a member appointed to the Board is four years, except that of the members first appointed to the Board—

[(i) five shall serve for terms of one year,

[(ii) five shall serve for terms of two years,

[(iii) five shall serve for terms of three years,

as designated by the Secretary at the time of appointment. Any member appointed to fill a vacancy occurring before the expiration of the term for which the predecessor of such member was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of the member's term until the successor of the member has taken office.

[(3)(A) Except as provided in subparagraph (B), members of the Board shall (i) be paid not more than the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Board, and (ii) while away from their homes or regular places of business and while serving in the business of the Board, be entitled to receive transportation expenses as prescribed by section 5703 of title 5, United States Code.

[(B) Members of the Board who are full-time officers or employees of the United States shall receive no additional pay, allowances, or benefits by reason of their service on the Board.

[(4) The Board may appoint such staff personnel as the Board considers appropriate.

[(5) The Secretary shall designate the chairman of the Board.

[(6) The Board shall meet at least three times each calendar year.

[(7) The Board shall report annually to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on its activities during the prior year and shall include in such report such recommendations for legislation and administrative action as it deems appropriate.

[(d) To educate the public with respect to the health hazards of alcoholism, alcohol abuse, and drug abuse, the Administrator shall take such actions as may be necessary to ensure the widespread dissemination of current publications of the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse relating to the most recent research findings with respect to such health hazards.

[(e)(1) There shall be in the administration an Associate Administrator for Prevention to whom the Administrator shall delegate the function of promoting the prevention research programs on the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse and coordinating such programs between the institutes and between the institutes and other public and private entities.

[(2) On or before January 1, 1984, and annually thereafter, the Administrator, acting through the Associate Administrator for Prevention, shall submit to the Congress a report describing the prevention activities (including preventive medicine and health promotion) undertaken by the administration, the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. The report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

[(f) The Administrator shall establish a process for the prompt and appropriate response to information provided the Administrator respecting (1) scientific fraud in connection with projects for which funds have been made available under this Act, and (2) incidences of violations of the rights of human subjects of research for which funds have been made available under this title. The process shall include procedures for the receiving of reports of such information from recipients of funds under this title and taking appropriate action with respect to such fraud and violations.

[(g) The Secretary, acting through the Administrator, shall make grants to schools of the health professionals and schools of social work to support the training of students in such schools in the identification and treatment of alcohol and drug abuse. Grants under this subsection shall be made from funds available under this title and section 303.

[(h)(1) The Administrator may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of service) the services of not more than 20 experts or consultants who have scientific or professional qualifications. Such experts and consultants shall be obtained for the Administration and for each of the research institutes under the Administrator.

[(2)(A) Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a)(1), 5724a(a)(3), and 5726(c) of title 5, United States Code.

[(B) Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1), unless and until the expert or consultant agrees in writing to complete the entire period of assignment or one year, whichever is shorter, unless separated or reassigned for reasons beyond the control of the expert or consultant that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.]

NATIONAL INSTITUTES ON ALCOHOL, DRUGS, AND MENTAL HEALTH

SEC. 501. (a) The National Institutes on Alcohol, Drugs, and Mental Health (hereafter referred to in this title as the "National Institutes") is an agency of the Service.

(b)(1) The following national research institutes are agencies of the National Institutes:

(A) The National Institute on Alcohol Abuse and Alcoholism.

(B) The National Institute on Drug Abuse.

(C) The National Institute of Mental Health.

(2) For purposes of this title, the term "national research institute" means a national research institute listed in paragraph (1). A reference to the National Institutes includes the national research institutes.

(c)(1) The National Institutes shall be headed by an Administrator (hereafter in this title referred to as the "Administrator") who shall be appointed by the President by and with the advice and consent of the Senate.

(2) The Administrator, with the approval of the Secretary, may appoint a Deputy Administrator and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out thorugh the National Institutes.

(d) The Secretary, acting through the Administrator—

(1) shall supervise the functions of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alocholism, and the National Institute on Drug Abuse in order to assure that the programs carried out through each such Institute receive appropriate and equitable support and that there is cooperation among the national research institutes in the implementation of such programs; and

(2) shall assure that research at or supported by the National Institutes and each of the national research institutes is subject to review in accordance with section 507 and is in complaince with section 509.

(e)(1) There shall be in the National Institutes an Associated Administrator for Prevention to whom the Administrator shall delegate the function of promoting the prevention research programs of the National Institite of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse and coordinating such programs between the national research institutes and between the national research Institutes and other public and private entities.

(2) By January 1, 1988, and every 3 years thereafter, the Administrator, acting through the Associate Administrator for Prevention, shall submit to the Congress a report describing the prevention activities (including preventive medicine and health promotion) undertaken by the National Institutes, the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. The report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

(f) The Administrator shall establish a process for the prompt and appropriate response to information provided the Administrator respecting (1) scientific fraud in connection with projects for which funds have been made available under this Act, and (2) incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such fraud and violations.

(g) The Secretary, acting through the Administrator, shall make grants to schools of the Health professions and school of social work to support the training of students in such schools in the identification and treatment of alcohol and drug abuse. Grants under this subsection shall be made from funds available under this title and section 303.

(h) To educate the public with respect to the heatlh hazards of alcoholism, alcohol abuse, and drug abuse, the Administrator shall take such actions as may be necessary to ensure the widespread dissemination of current publications of the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse relating to the most recent research findings with respect to such health hazards.

(i)(1) The Administrator may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than 20 experts or consultants who have scientific or professional qualifications. Such experts and consultants shall be obtained for the National Institutes and for each of the national research institutes.

(2)(A) Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724(a)(1), 5724(a)(3), and 5726(c) of title 5, United States Code.

(B) Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1), unless and until the expert or consultant agrees in writing to complete the entire period of assignment or one year, whichever is shorter, unless separated or reassigned for reasons beyond the control the expert or consultant that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under the subparagraph.

(j) In carrying out this Act, the Administrator may accept voluntary and uncompensated services for the National Institutes and for each of the national research institutes.

(k)(1) The Secretary shall—

(A) develop and publish information respecting the causes of suicide among individuals under the age of 21 and the means of preventing suicide among such individuals, and

(B) make such information generally available to the public and health professionals.

(2) By January 1, 1988, and every 3 years thereafter, the Secretary shall report to the Congress on the activities undertaken under paragraph (1) during the period reported on and shall include in each such report an assessment of the effectivness of such activities.

(l)(1) The Alcohol, Drug Abuse, and Mental Health Advisory Board (hereafter in this subsection referred to as the "Board") shall—

(A) periodically assess the national needs for alcoholism, alcohol abuse, drug abuse, and mental health services and the extent to which those needs are being met by State, local, and private programs and programs receiving funds under this title and part B of title XIX; and

(B) provide advice to the Secretary and the Administrator respecting activities carried out under this title and part B of title XIX.

(2)(A) The Board shall consist of 15 members appointed by the Secretary and such ex officio members from the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health as the Secretary may designate. Of the members appointed to the Board, at least 6 members shall represent State and private, nonprofit providers of prevention and treatment services for alcoholism, alcohol abuse, drug abuse, and mental illness, at least 6 members shall be individuals with expertise in public education and prevention services for alcoholism, alcohol abuse, drug abuse, and mental illness, and at least 3 members shall be appointed from members of the general public who are knowledgeable about alcoholism, alcohol abuse, drug abuse, and mental illness.

(B) The term of office of a member appointed to the Board is 4 years, except that of the members first apointed to the Board—

(i) 5 shall serve for terms of 1 year;

(ii) 5 shall serve for terms of 2 years; and

(iii) 5 shall serve for terms of 3 years,

as designated by the secretary at the time of appointment. Any member appointed to fill a vacancy occurring before the expiration of the term for which the predecessor of such member was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of the member's term unitl the successor of the member has taken office.

(3)(A) Except as provided in subparagraph (B), members of the Board shall (i) be paid not more than the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Board, and (ii) while away from their homes or regular places of business and while serving in the business of the Board, be entitled to receive transportation expenses as prescribed by section 5703 of title 5, United States Code.

(B) Members of the Board who are full-time officers or employees of the United States shall receive no additional pay, allowances, or benefits by reason of their service on the Board.

(4) The Board may appoint such staff personnel as the Board considers appropriate.

(5) The Secretary shall designate the chairman of the Board.

(6) The Board shall meet at least 3 times each calendar year.

(7) The Board shall report annually to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on its activities during the prior year and shall include in such report such recommendations for legislation and administrative action as it deems appropriate.

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NATIONAL INSTITUTE ON DRUG ABUSE

SEC. 503. (a) There is established the National Institute on Drug Abuse (hereinafter in this section referred to as the Institute) to administer the programs and authorities relating to drug abuse assigned to the Secretary by this Act. The Secretary, acting through the Institute, shall, in carrying out the purposes of sections 301, 302, and 303 with respect to drug abuse, develop and conduct comprehensive health, education, training, research, and planning programs for the prevention and treatment of drug abuse and for the rehabilitation of drug abusers. The Secretary shall carry out through the Institute the administrative and financial management, policy development and planning, evaluation, and public information functions which are required for the implementation of such programs and authorities.

(b)(1) The Institute shall be under the direction of a Director who shall be appointed by the Secretary.

(2) The Director, with the approval of the Secretary, may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the programs and authorities to be carried out through the Institute.

(c) The programs of the Institute shall be administered so as to encourage the broadest possible participation of professionals and paraprofessionals in the fields of medicine, science, the social sciences, and other related disciplines.

(d) The Secretary shall—

(1) operate an information center for the collection, preparation, and dissemination of all information relating to drug abuse prevention functions, including information concerning State and local drug abuse treatment plans, and the availability of treatment resources, training and educational programs, statistics, research, and other pertinent data and information;

(2) investigate and publish information concerning uniform methodology and technology for determining the extent and kind of drug use by individuals and effects which individuals are likely to experience from such use;

(3) gather and publish statistics pertaining to drug abuse and promulgate regulations specifying uniform statistics to be furnished, records to be maintained, and reports to be submitted, on a voluntary basis by public and private entities and individuals respecting drug abuse; and

(4) prepare for distribution announcements for television to educate the public concerning the dangers resulting from the consumption of drugs and, to the extent feasible, use appropriate private organizations and business concerns in the preparation of such announcements.

(e)(1) The Secretary, acting through the Institute and in consultation with the Director of the Office on Smoking and Health, shall prepare for distribution announcements for television to educate the public, particularly women, concerning the dangers resulting from cigarette smoking by women. In the preparation of such announcements, the Secretary shall, to the extent feasible, use appropriate private organizations and business concerns.

(2) Of the amount appropriated under section 517 for each of the fiscal years 1987, 1988, and 1989, $250,000 shall be available to carry out paragraph (1) for such fiscal year.

NATIONAL INSTITUTE OF MENTAL HEALTH

SEC. 504. (a) There is established the National Institute of Mental Health (hereinafter in this part referred to as the "Institute") to administer the programs and authorities of the Secretary with respect to mental health. The Secretary, acting through the Institute, shall, in carrying out the purposes of sections 301 and 303 of this Act with respect to mental illness, develop and conduct comprehensive health, education, training, research, and planning programs for the prevention and treatment of mental illness and for the rehabilitation of the mentally ill. The Secretary shall carry out through the Institute the administrative and financial management, policy development and planning, evaluation, and public information functions which are required for the implementation of such programs and authorities.

(b)(1) The Institute shall be under the direction of a Director who shall be appointed by the Secretary.

(2) The Director, with the approval of the Secretary, may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the programs and authorities to be carried out through the Institute.

(c) The programs to be carried out through the Institute shall be administered so as to encourage the broadest possible participation of professionals and paraprofessionals in the fields of medicine, science, the social sciences, and other related disciplines.

(d) The Director shall designate an administrative unit in the Institute to—

(1) design national goals and establish national priorities for—

(A) the prevention of mental illness, and

(B) the promotion of mental health,

(2) encourage and assist local entities and State agencies to achieve the goals and priorities described in paragraph (1), and

(3) develop and coordinate Federal prevention policies and programs and to assure increased focus on the prevention of mental illness and the promotion of mental health.

(e)(1) The Director of the National Institute of Mental Health shall designate an Associate Director for Special Populations.

(2) The Secretary, acting through the Associate Director for Special Populations, shall—

(A) develop and coordinate prevention, treatment, research, and administrative policies and programs to assure increased emphasis on the mental health needs of women and minority populations;

(B) support programs and projects relating to the delivery of mental health services to women and minority populations, including demonstration programs and projects;

(C) develop a plan to increase the representation of women and minority populations in mental health service delivery and manpower programs;

(D) support programs of basic and applied social and behavioral research on the mental health problems of women and minority populations;

(E) study the effects of discrimination on institutions and individuals, including majority institutions and individuals;

(F) develop systems to assist women and minority populations in adapting to, and coping with, the effects of discrimination;

(G) support and develop research, demonstration, and training programs designed to eliminate institutional discrimination; and

(H) provide increased emphasis on the concerns of women and minority populations in training programs, service delivery programs, and research endeavors of the Institute.

(f)(1) The Secretary, acting through the Director, may make grants to States, political subdivisions of States, and private nonprofit agencies for mental health services demonstration projects for the planning, coordination, and improvement of community services for chronically mentally ill individuals, seriously mentally disturbed children, and elderly individuals, and for the conduct of research concerning such services.

(2) The Secretary may make a grant under paragraph (1) for not more than three consecutive one-year periods, except that the Secretary may waive the limitation of this paragraph with respect to a particular grant if the Secretary determines that extenuating circumstances exist which merit such waiver.

(3) For purposes of paragraphs (1) and (2) there are authorized to be appropriated $20,000,000 for each of the fiscal years 1985, 1986, and 1987.

(g) The Secretary, acting through the Director, may make grants to States for the purpose of developing State comprehensive mental health plans referred to in section 1916(e).

ADVISORY COUNCILS

SEC. 505. (a)(1) The Secretary shall appoint an advisory council for the National Institute on Alcohol Abuse and Alcoholism, for the National Institute on Drug Abuse, and for the National Institute of Mental Health. Each such advisory council shall advise, consult with, and make recommendations to the Secretary and the Director of the national research institute for which it was appointed on—

(A) matters relating to the activities carried out by and through the Institute and the policies respecting such activities; and

(B) matters relating to activities carried out by the Secretary and the National Institutes respecting the disease, disorder, or other aspect of human health with which the advisory council is concerned.

(2) Each advisory council for a national research institute may recommend to the Secretary acceptance, in accordance with section 2101, of conditional gifts for—

(A) study, investigation, or research respecting the diseases, disorders, or other aspect of human health with respect to which the institute was established;

(B) the acquisition of grounds for the institute; or

(C) the construction, equipping, or maintenance of facilities for the institute.

(3) Each advisory council for a national research institute—

(A)(i) may on the basis of the materials provided under section 507(d)(2) respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research;

(ii) shall review applications for grants and cooperative agreements for research or training and for which advisory council approval is required under section 507(e)(2), and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge; and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspect of human health with respect to which the national research institute was established and with the approval of the Director of the institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b)(1) Each advisory council shall consist of ex officio members and not more than 12 members appointed by the Secretary.

(2) The ex officio members of an advisory council shall consist of—

(A) the Secretary, the Administrator, the Director of the national research institute for which the advisory council is established, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) Such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

(A) Nine of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the national research institute for which the advisory council is established.

(B) Three of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, public relations, law, health policy, economics, and management.

(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including travel time) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule.

(c) The term of office of an appointed member of an advisory council is 4 years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of 4 years may not be reappointed to an advisory council before 2 years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) The chairman of an advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the national research institute for which the advisory council is established to be the chairman of the advisory concil. The term or office of chairman shall be 2 years.

(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established, but at least 3 times each fiscal year. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

(f) The Director of the national research institute for which an advisory council is established shall designate a member of the staff of the institute to serve as the executive secretary of the advisory council. The Director of such institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of such institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

REPORTS ON ALCOHOLISM, ALCOHOL ABUSE, AND DRUG ABUSE

SEC. [505] *506.* (a) The Secretary shall submit to Congress on or before January 15, 1984, and every three years thereafter a report—

(1) containing current information on the health consequences of using alcoholic beverages,

(2) containing a description of current research findings made with respect to alcohol abuse and alcoholism, and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

(b) The Secretary shall submit to Congress on or before January 15, 1984, an every three years thereafter a report—

(1) describing the health consequences and extent of drug abuse in the United States;

(2) describing current research findings made with respect to drug abuse, including current findings on the health effects of marihuana and the addictive property of tobacco; and

(3) containing such recommendations for legislation and administrative action as the Secretary may deem appropriate.

SEC. [506] *507.* (a) The Secretary, after consultation with the Directors of the National Insititute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse shall by regulation require appropriate technical and scientific peer review of biomedical and behavioral research and development grants, cooperative agreements, and contracts to be administered through the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse.

(b) Regulations promulgated under subsection (a) shall require that the review of grants, cooperative agreements, and contracts required by the regulations be conducted—

(1) in a manner consistent with the system for scientific peer review applicable on the date of the enactment of this section to grants, cooperative agreements, and contracts under this Act for biomedical and behavioral research, and

(2) to the extent practical, by peer review groups performing such review on or before such date.

(c) The members of any peer review group established under such regulations shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group and not more than one-fourth of the members of any peer review group established under such regulations shall be officers or employees of the United States.

(d) The Administrator [of the administration] shall establish procedures for periodic, technical, and scientific peer review of research at the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. Such procedures shall require that—

(1) the reviewing entity be provided a written description of the research to be reviewed; and

(2) the reviewing entity provide the advisory council of the institute involved with such description and the results of the review by the entity.

(e)(1) If the direct cost of a grant, cooperative agreement, or contract (described in subsection (a)) to be made does not exceed $50,000, the Secretary may make such grant, cooperative agreement, or contract only if such grant, cooperative agreement, or contract is recommended after technical and scientific peer review required by regulations under subsections (a) and (b).

(2) If the direct cost of a grant, cooperative agreement, or contract (described in subsection (a)) to be made exceeds $50,000, the Secretary may make such grant, cooperative agreement, or contract only if such grant, cooperative agreement, or contract is recommended—

(A) after technical and scientific peer review required by regulations under subsections (a) and (b), and

(B) by the National Advisory Council on Alcohol Abuse and Alcoholism, the National Advisory Council on Drug Abuse, or the National Mental Health Advisory Council, as is appropriate.

RESEARCH ON PUBLIC HEALTH EMERGENCIES

SEC. 508. (a) If the Secretary determines, after consultation with the Administrator, the Commissioner of Food and Drugs, or the Director of the Centers for Disease Control, that a disease or disorder within the jurisdiction of a national research institute constitutes a public health emergency, the Secretary, acting through the Administrator—

(1) shall expedite the review by advisory councils and by peer review groups of applications for grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 3709 of the Revised Statutes (41 U.S.C. 5) respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

(b) Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) in such fiscal year.

ANIMALS IN RESEARCH

SEC. 509. (a) The Secretary, acting through the Administrator, shall establish guidelines for the following:

(1) The proper care of animals to be used in research conducted by and through agencies of the National Institutes.

(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require—

(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

(3) The organization and operation of animal care committees in accordance with subsection (b).

(b)(1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts research with funds provided under this title to assure compliance with the guidelines established under subsection (a).

(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than 3 members, and shall include at least 1 individual who has no association with such entity and at least 1 doctor of veterinary medicine.

(3) Each animal care committee of a research entity shall—

(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semiannually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

(B) keep appropriate records of reviews conducted under subparagraph (A); and

(C) for each review conducted under subparagraph (A), file with the Administrator at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

(c) The Administrator shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the Administrator or any agency of the National Institutes to include in its application or contract proposal, submitted after the expiration of the 12-month period beginning on the date of enactment of this section—

(1) assurances satisfactory to the Administrator that—

(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or

testing methods that limit the use of animals or limit animal distress; and

(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

(d) If the Administrator determines that—

(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do not meet applicable guidelines established under subsection (a);

(2) the entity has been notified by the Administrator of such determination and has been given a reasonable opportunity to take corrective action; and

(3) no action has been taken by the entity to correct such conditions;

the Administrator shall suspend or revoke such grant or contract under such conditions as the Administrator determines appropriate.

(e) No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.

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AUTHORIZATIONS OF APPROPRIATIONS

[SEC. 513. There are authorized to be appropriated to carry out this subpart $33,484,000 for fiscal year 1983, $45,790,000 for fiscal year 1984, $52,000,000 for fiscal year 1985, and $61,000,000 for fiscal year 1986.]

SEC. 513. There are authorized to be appropriated to carry out this subpart $69,000,000 for fiscal year 1987 and such sums as may be necessary for fiscal years 1988, 1989, 1990, and 1991.

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AUTHORIZATION OF APPROPRIATIONS

[SEC. 517. There are authorized to carry out this subpart $68,000,000 for fiscal year 1985 and $74,000,000 for fiscal year 1986.]

SEC. 517. There are authorized to be appropriated to carry out section 503(e) and this subpart $83,000,000 for fiscal year 1987 and such sums as may be necessary for fiscal years 1988, 1989, 1990, and 1991.

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SEC. 523. (a)-(d) * * *

(e)*(1)* The prohibitions of this section do not apply to any interchange of records—

[(1)](A) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

[(2)](B) between such components and the Armed Forces.

(2) The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State authorities.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(h) The Administrator of Veterans' Affairs, through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations prescribed by the Secretary under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from alcohol abuse or alcoholism. In prescribing and implementing regulations pursuant to this subsection, the Administrator shall, from time to time, consult with the Secretary in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

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SEC. 527. (a)–(d) * * *

(e)*(1)* The prohibitions of this section do not apply to any interchange of records—

[(1)](A) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

[(2)](B) between such components and the Armed Forces,

(2) The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State authorities.

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, includ-

ing procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(h) The Administrator of Veterans' Affairs, through the Chief Medical Director, shall, to the maximum feasible extent consistent with their responsibilities under title 38, United States Code, prescribe regulations making applicable the regulations established by the Secretary under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from drug abuse. In prescribing and implementing regulations pursuant to this subsection, the Administrator shall, from time to time, consult with the Secretary in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

ALCOHOL WARNING LABELS

SEC. 11. Title V of the Public Health Service Act is amended by adding at the end thereof the following new part:

PART D—PUBLIC AWARENESS CONCERNING THE HEALTH EFFECTS OF ALCOHOLIC BEVERAGE CONSUMPTION

PUBLIC AWARENESS

SEC. 531. (a) It shall be unlawful for any person to manufacture, import, distribute, sell, ship, package or deliver for sale, distribution, or shipment, or otherwise introduce in commerce, in the United States, any alcoholic beverage during a calendar year unless the container of such beverage has a label bearing one of the following statements:

(1) "WARNING: THE SURGEON GENERAL HAS DETERMINED THAT THE CONSUMPTION OF THIS PRODUCT, WHICH CONTAINS ALCOHOL, DURING PREGNANCY CAN CAUSE BIRTH DEFECTS."

(2) "WARNING: DRINKING THIS PRODUCT, WHICH CONTAINS ALCOHOL, CAN IMPAIR YOUR ABILITY TO DRIVE A CAR OR OPERATE MACHINERY."

(3) "WARNING: THIS PRODUCT CONTAINS ALCOHOL AND IS PARTICULARLY HAZARDOUS IN COMBINATION WITH SOME DRUGS."

(4) "WARNING: THE CONSUMPTION OF THIS PRODUCT, WHICH CONTAINS ALCOHOL, CAN INCREASE THE RISK OF DEVELOPING HYPERTENSION, LIVER DISEASE, AND CANCER."

(5) The statement, if any, prescribed by the Surgeon General under subsection (b)(2) for such calendar year.

(b)(1) The Director of the National Institute on Alcohol Abuse and Alcoholism shall provide for the conduct of research concerning the chronic and acute effects on health resulting from the consumption of alcoholic beverages. By September 1 of each year, the Director shall, based on the results of the research conducted under the preceding sentence, make recommendations to the Surgeon General for two statements concerning the health effects of the consumption of alcoholic beverages which the Director proposes be prescribed by the

Surgeon General for purposes of subsection (a)(5) for the calendar year beginning on January 1 of the succeeding year. The NIAAA shall consider and make recommendations on at least one statement regarding the hazard of immediate death from rapid consumption of alcohol.

(2) By October 1 of each year, the Surgeon General may select one of the statements recommended during such year by the Director of the National Institute on Alcohol Abuse and Alcoholism pursuant to paragraph (1). If the Surgeon General selects one such statement, the Surgeon General shall prescribe regulations requiring that, for purposes of subsection (a)(5), such statement shall, for the calendar year beginning on January 1 of the succeeding year, be one of the statements required under subsection (a) to be specified on a label on the container of an alcoholic beverage.

(c) The label required by subsection (a) shall be located in a conspicuous and prominent place on the container of an alcoholic beverage. The statement required by such subsection shall appear in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on such container.

(d) Each statement required by subsection (a) shall—

(1) be randomly displayed by a manufacturer, packager, or importer of an alcoholic beverage in each calendar year in as equal a number of times as is possible on each brand of the beverage; and

(2) be randomly distributed in all parts of the United States in which such brand is marketed.

(e) No statement relating to the consumption of alcoholic beverages and health, other than the statements required by subsection (a), shall be required on any container of an alcoholic beverage.

(f) Any person who violates the provisions of this section shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than $10,000.

(g) The several district courts of the United States are invested with jurisdiction, for cause shown, to prevent and restrain violations of this section upon the application of the Attorney General of the United States acting through the several United States attorneys in their several districts.

(h) Alcoholic beverages manufactured, imported, distributed, sold, shipped, packaged, or delivered (1) for export from the United States or (2) for delivery to a vessel or aircraft, as supplies, for consumption beyond the jurisdiction of the internal revenue laws of the United States shall be exempt from the requirements of this section, but such exemptions shall not apply to alcoholic beverages manufactured, imported, distributed, sold, shipped, or packaged or delivered for sale, distribution, or shipment to members or units of the Armed Forces of the United States located outside of the United States.

(i) Nothing in this section shall be construed to relieve any person from any liability under Federal or State law to any other person.

(j) For purposes of this section—

(1) the term "alcoholic beverage" includes distilled spirits, wine, and malt beverages;

(2) the term "commerce" has the same meaning as in section 3(2) of the Federal Cigarette Labeling and Advertising Act;

(3) the term "container" means any container, irrespective of the material from which made, for use for the sale of any alcoholic beverage;

(4) the term "distilled spirits" means ethyl alcohol, hydrated oxide of ethyl, spirits of wine, whiskey, rum, brandy, gin, and other distilled spirits, including all dilutions and mixtures thereof, for nonindustrial use;

(5) the term "malt beverage" means a beverage made by the alcoholic fermentation of an infusion or decoction, or combination of both, in potable brewing water, of malted barley with hops, or their parts, or their products, and with or without other malted cereals, and with or without the addition of unmalted or prepared cereals, other carbohydrates or products prepared therefrom, and with or without the addition of carbon dioxide, and with or without other wholesome products suitable for human food consumption;

(6) the term "person" has the same meaning as in section 3(5) of such Act;

(7) the terms "sale" and "distribution" include sampling or any other distribution not for sale;

(8) the term "United States" has the same meaning as in section 3(3) of such Act; and

(9) the term "wine" has the same meaning as in section 17(a)(6) of the Federal Alcohol Administration Act.

Other Acts Affected by These Changes

Federal Alcohol Administration Act

(27 U.S.C. 205)

27 U.S.C. 205 (a)-(d) * * *

(e) Labeling

To sell or ship or deliver for sale or shipment, or otherwise introduce in interstate or foreign commerce, or to receive therein, or to remove from customs custody for consumption any distilled spirits, wine, or malt beverages in bottles, unless such products are bottled, packaged, and labeled in conformity with such regulations, to be prescribed by the Secretary of the Treasury, with respect to packaging, marking, branding, and labeling and size and fill of container (1) as will prohibit deception of the consumer with respect to such products or the quantity thereof and as will prohibit, irrespective of falsity, such statements relating to age, manufacturing processes, analyses, guarantees, and scientific or irrelevant matters as the Secretary of the Treasury finds to be likely to mislead the consumer; (2) as will provide the consumer with adequate information as to the identity and quality of the products, the alcoholic content thereof [except that statements of, or statements likely to be considered as statements of, alcoholic content of malt beverages are prohibited unless required by State law and] except that, in case of wines, statements of alcoholic content shall be required only for wines containing more than 14 per centum of alcohol by volume *and except that subsection (g) of this section shall apply in lieu of this clause to statements of, or statements likely to be considered as*

statements of, alcoholic content of malt beverages, the net contents of the package, and the manufacturer or bottler or importer of the product; (3) as will require an accurate statement, in the case of distilled spirits (other than cordials, liqueurs, and specialties) produced by blending or rectification, if neutral spirits have been used in the production thereof, informing the consumer of the percentage of neutral spirits so used and of the name of the commodity from which such neutral spirits have been distilled, or in case of neutral spirits or of gin produced by a process of continuous distillation, the name of the commodity from which distilled; (4) as will prohibit statements on the label that are disparaging of a competitor's products or are false, misleading, obscene, or indecent; and (5) as will prevent deception of the consumer by use of a trade or brand name that is the name of any living individual of public prominence, or existing private or public organization, or is a name that is in simulation or is an abbreviation thereof, and as will prevent the use of a graphic, pictorial, or emblematic representation of any such individual or organization, if the use of such name or representation is likely falsely to lead the consumer to believe that the product has been indorsed, made, or used by, or produced for, or under the supervision of, or in accordance with the specifications of, such individual or organization: *Provided,* That this clause shall not apply to the use of the name of any person engaged in business as a distiller, brewer, rectifier, blender, or other producer, or as an importer, wholesaler, retailer, bottler, or warehouseman, of distilled spirits, wine, or malt beverages, nor to the use by any person of a trade or brand name used by him or his predecessor in interest prior to August 19, 1935; including regulations requiring, at time of release from customs custody, certificates issued by foreign governments covering origin, age, and identity of imported products: *Provided further,* That nothing herein nor any decision, ruling, or regulation of any Department of the Government shall deny the right of any person to use any trade name or brand of foreign origin not presently effectively registered in the United States Patent and Trademark Office which has been used by such person or predecessors in the United States for a period of at least five years last past, if the use of such name or brand is qualified by the name of the locality in the United States in which the product is produced, and, in the case of the use of such name or brand on any label or in any advertisement, if such qualification is as conspicuous as such name or brand.

It shall be unlawful for any person to alter, mutilate, destroy, obliterate, or remove any mark, brand, or label upon distilled spirits, wine, or malt beverages held for sale in interstate or foreign commerce or after shipment therein, except as authorized by Federal law or except pursuant to regulations of the Secretary of the Treasury authorizing relabeling for purposes of compliance with the reqirements of this subsection or of State law.

In order to prevent the sale or shipment or other introduction of distilled spirits, wine, or malt beverages in interstate or foreign commerce, if bottled, packaged, or labeled in violation of the requirements of this subsection, (1) no bottler or distilled spirits, no producer, blender, or wholesaler of wine, or proprietor of a bonded wine storeroom, and no brewer or wholesaler of malt beverages

shall bottle, and (2) no person shall remove from customs custody, in bottles, for sale or any other commercial purpose, distilled spirits, wine, or malt beverages, respectively, after such date as the Secretary of the Treasury fixes as the earliest practicable date for the application of the provisions of this subsection to any class of such persons (but not later than August 15, 1936, in the case of distilled spirits, and December 15, 1936, in the case of wine and malt beverages, and only after thirty days' public notice), unless, upon application to the Secretary of the Treasury, he has obtained and has in his possession a certificate of label approval covering the distilled spirits, wine, or malt beverages, issued by the Secretary in such manner and form as he shall by regulations prescribe: *Provided,* That any such bottler of distilled spirits, or producer, blender, or wholesaler of wine, or proprietor of a bonded wine storeroom, or brewer or wholesaler of malt beverages shall be exempt from the requirements of this subsection if, upon application to the Secretary, he shows to the satisfaction of the Secretary that the distilled spirits, wine or malt beverages to be bottled by the applicant are not to sold, or offered for sale, or shipped or delivered for shipment, or otherwise introduced, in interstate or foreign commerce. Officers of internal revenue are authorized and directed to withhold the release of distilled spirits from the bottling plant unless such certificates have been obtained, or unless the application of the bottler for exemption has been granted by the Secretary; and customs officers are authorizes and directed to withhold the release from customs custody of distilled spirits, wine and malt beverages, unless such certificates have been obtained. The District Courts of the United States, and the United States court for any Territory shall have jurisdiction of suits enjoin, annual, or suspend in whole or in part any final action by the Secretary upon any application under this subsection; or

(f) Advertising

To publish or disseminate or cause to be published or disseminated by radio broadcast, or in any newspaper, periodical or other publication or by any sign or outdoor advertisement or any other printed or graphic matter, any advertisement of distilled spirits, wine, or malt beverages, if such advertisement is in, or is calculated to induce sales in, interstate or foreign commerce, or is disseminated by mail, unless such advertisement is in conformity with such regulations, to be prescribed by the Secretary of the Treasury, (1) as will prevent deception of the consumer with respect to the products advertised and as will prohibit, irrespective of falsity, such statements relating to age, manufacturing processes, analyses, guaranties, and scientific or irrelevant matters as the Secretary of the Treasury finds to be likely to mislead the consumer; (2) as will provide the consumer with adequate information as to the identity and quality of the products advertised, the alcoholic content thereof (except the statements of, statements likely to be considered as statements of, alcoholic content of [malt beverages and] *malt beverages are permitted, but are not required, and such statements with respect to* wines are prohibited), and the person responsible for the advertisement; (3) as will require an accurate statement, in the case of distilled spirits (other than cordials, liqueurs, and special-

ties) produced by blending or rectification, if neutral spirits have been used in the production thereof, informing the consumer of the percentage of neutral spirits so used and of the name of the commodity from which such neutral spirits have been distilled, or in case of neutral spirits or of gin produced by a process of continuous distillation, the name of the commodity from which distilled; (4) as will prohibit statements that are disparaging of a competitor's products or are false, misleading, obscene, or indecent; (5) as will prevent statements inconsistent with any statement on the labeling of the products advertised. This subsection shall not apply to outdoor advertising in place or June 18, 1935, but shall apply upon replacement, restoration, or renovation of any such advertising. The prohibitions of this subsection and regulation thereunder shall not apply to the publisher of any newspaper, periodicial, or other publication, or radio broadcaster, unless such publisher or radio broadcaster is engaged in business as a distiller, brewer, rectifier, or other producer, or as an importer or wholesaler, of distilled spirits, wine, or malt beverages, or as a bottler, or warehouseman and bottler, or distilled spirits, directly or indirectly or through an affiliate.

The provisions of subsections (a), (b), and (c) of this section shall not apply to any act done by an agency of a State or political subdivision thereof, or by any officer or employee of such agency.

In the case of malt beverages, the provisions of subsections (a), (b), (c), and (d) of this section shall apply to transactions between a retailer or trade buyer in any State and a brewer, importer or wholesaler of malt beverages outside such State only to the extent that the law of such State imposes similar requirements with resepct to similar transactions between a retailer or trade buyer in such State and a brewer, importer, or wholesaler of malt beverages in such State, as the case may be. In the case of malt beverages, the provsions of this subsection and subsection (e) of this section shall apply to the labeling of malt beverages sold or shipped or delivered for shipment or otherwise introduced into or received in any State from any place outside thereof, or the advertising of malt beverages intended to be sold or shipped or delivered for shipment or otherwise introduced into or received in any State from any place outside thereof, only to the extent that the law of such State imposes similar requirements with respect to the labeling or advertising, as the case may be, of malt beverages not sold or shipped or delivered for shipment or otherwise introduced into or received in such State any place outside thereof.

The Secretary of the Treasury shall give reasonable public notice, and afford to interested parties opportunity for hearing, prior to prescribing regulations to carry out the provisions of this section.

(g) Alcholic content of malt beverages

To sell or ship or deliver for sale or shipment, or otherwise introduce in interstate commerce, or receive therein, or to remove from coustoms custody for consumption, any malt beverages in bottles, unless the label on the bottle of any such beverage bears an accurate statement of the alcholic content of such beverage.

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§ 211. Miscellaneous provisions

(a) Definitions

As used in this chapter—

(1) The term "United States" means the several States and Territories and the District of Columbia; the term "State" includes a Territory and the District of Columbia; and the term "Territory" means Alaska, Hawaii, and Puerto Rico.

(2) The term "interstate of foreign commerce" means commerce between any State and any place outside thereof, or commerce within any Territory or the District of Columbia, or between points within the same State but through any place outside thereof.

(3) The term "person" means individual, partnership, joint stock company, business trust, association, coprporation, or other form of business enterprise, including a receiver, trustee, or liquidating agent and including an officer or employee of any agency of a State or political subdivision thereof; and the term "trade buyer" means any person who is a wholesaler or retailer.

(4) The term "affiliate" means any one of two or more persons if one of such persons has actual or legal control, directly or indirectly, whether by stock ownership or otherwise, of the other or others of such persons; and any one of two or more persons subject to common control, actual or legal, directly or indirectly, whether by stock ownership or otherwise.

(5) The term "distilled spirits" means ethyl alcohol, hydrated oxide of ethyl, spirits of wine, whiskey, rum, brandy, gin, and other distilled spirits, including all dilutions and mixtures thereof, for non-industrial use.

(6) The term "wine" means (1) wine as defined in sections 610 and 617 of the Revenue Act of 1918 as now in force or hereafter amended, and (2) other alcoholic beverages not so defined, but made in the manner of wine, including sparkling and carbonated wine, wine made from condensed grape must, wine made from other agricultural products than the juice of sound, ripe grapes, imitation wine, compounds sold as wine, vermouth, cider, perry and sake; in each instance only if containing not less than 7 per centum and not more than 24 per centum of alcohol by volume, and if for non-industrial use.

(7) The term "malt beverage" means a beverage made by the alcoholic fermentation of an infusion or decoction, or combination of both, in potable brewing water, of malted barley with hops, or their parts, or their products, and with or without other malted cereals, and with or without the addition of unmalted or prepared cereals, other carbohydrates or products prepared therefrom, and with or without the addition of carbon dioxide, and with or without other wholesome products suitable for human food consumption.

(8) The term "bottle" means any container, irrespective of the material from which made, for use for the sale of distilled spirits, wine, or malt beverages at retail.

(9) The term "alcoholic content" means, with respect to malt beverages, the percentage by volume of the beverage which is comprised of alcohol.

(B) Within one year after the date of enactment of this Act, the Secretary of the Treasury shall revise the regulations promulgated under the Federal Alcohol Administration Act to carry out the amendments made by this subsection.

(b)(1) The amendments made by this subsection shall take effect one year after the date of enactment of this Act.

(b) Right to amend or repeal

The right to amend or repeal the provisions of this chapter is expressly reserved.

(c) Separability of provisions

If any provision of this chapter, or the application of such provision to any person or circumstance, is held invalid, the remainder of the chapter and the application of such provisions to persons or circumstances other than those as to which it is held invalid, shall not be affected thereby.

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